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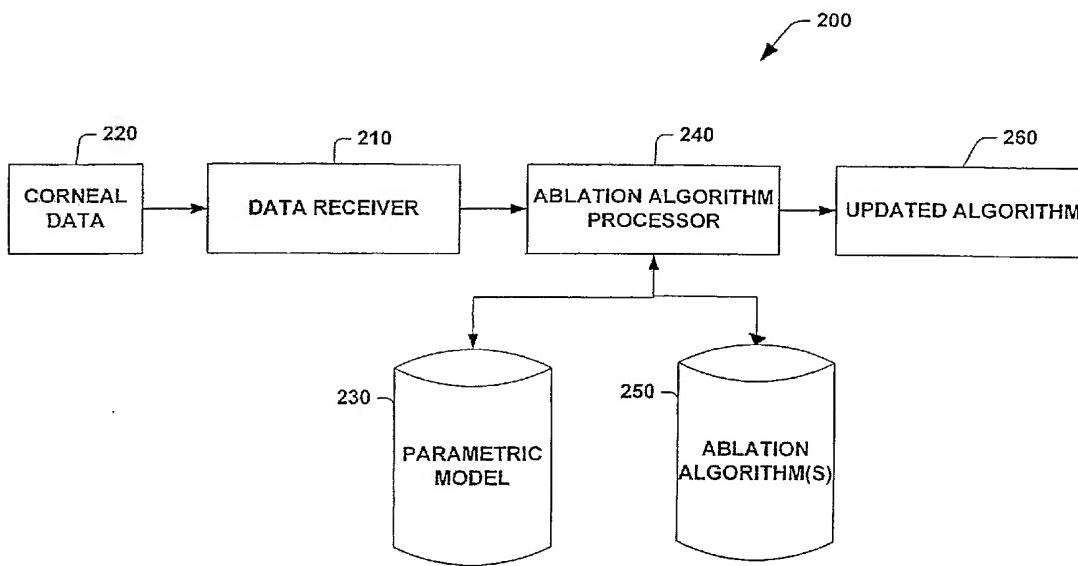
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(54) Title: PARAMETRIC MODEL BASED ABLATIVE SURGICAL SYSTEMS AND METHODS



(57) Abstract: Example systems and methods for performing individually customized corneal ablative surgery is presented. The example systems and methods rely on a parametric model that correlates corneal measurements with predicted post-operative results and algorithm updates that facilitate achieving desired post-operative results.

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## **PARAMETRIC MODEL BASED ABLATIVE SURGICAL SYSTEMS AND METHODS**

The methods, systems, computer readable media and so on described herein relate generally to eye surgery related computer programming and more particularly to updating a corneal ablative algorithm based on correlations between pre-operative measurements and predicted post-operative results as modeled in a parametric model.

More than one million laser refractive surgeries based on a mean population response eye are performed every year to correct myopia. Of the many individuals treated with conventional procedures, about 15% to 50% do not achieve 20/20 vision due, at least in part, to the relationship of the patient eye to the mean population response eye and the dependence of refractive procedures on the mean population response eye. Additionally, many individuals cannot benefit from corneal ablative techniques because their eyes do not fall within parameters modeled by the mean population response eye. Although a greater percentage of individuals treated with customized or wavefront guided procedures achieve 20/20 vision than with conventional procedures, visual aberrations are still induced in a significant number of patients, which degrade vision from the planned outcome of a reduction in aberrations over the pre-operative state.

Initial attempts at photorefractive keratectomy (PRK) used a model presented in 1988 by Munnerlyn, et al. The cornea was modeled as two refracting surfaces with a bulk material in between the two refracting surfaces where there was a known index of refraction. In treating myopia, the goal was to increase the anterior radius of curvature, thus decreasing the curvature and thus power of the anterior surface as illustrated in Figure

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1. A simple geometric formula resulted, which assumed the targeted corneal shape was a function of the ablation profile. This is the “shape subtraction” paradigm, based on a geometric approach to tissue removal and secondary curvature change, where the final corneal shape is assumed to be determined by how much tissue is subtracted by a laser.
- 5     Essentially, this model treats the cornea as a piece of plastic to be sculpted into an ideal surface shape by laser ablation.

The equations described by Munnerlyn, et al. still serve as a starting point for ablation algorithms. However, PRK, Laser Epithelial Keratomileusis (LASEK), and Laser Assisted in-Situ Keratomileusis (LASIK) fail to consistently produce expected refractive

10    outcomes.

The following presents a simplified summary of methods, systems, and computer readable media employed to customize ablative algorithms based on a parametric model that correlates measurements taken pre-operatively and/or during surgery with predicted post-operative results to facilitate providing a basic understanding of these items. This

15    summary is not an extensive overview and is not intended to identify key or critical elements of the methods, systems, and computer readable media or to delineate the scope of these items. This summary provides a conceptual introduction in a simplified form as a prelude to the more detailed description that is presented later.

This application concerns updating an ablative algorithm based on individual

20    measurements taken before and/or during surgery. The measurements have been correlated with desired predicted post-operative results. Example measurements include, but are not limited to, modulus of elasticity, corneal acoustic response to ultrasonic excitation, pachymetric profile in multiple meridians, pachymetric asymmetry between

vertical and horizontal meridians, magnitude of difference in pachymetry between center and periphery, corneal width, anterior chamber angle and depth, corneal curvature profile in multiple meridians, magnitude of astigmatism, difference in astigmatism between center and periphery topographic response to the cutting of a LASIK flap. Example correlations

5 include, but are not limited to, greater peripheral thickness causing greater spherical aberration. For example, measuring peripheral thickness facilitates predicting post-operative spherical aberration, thus a peripheral thickness measurement in the range {a, b} suggests (taking action to increase peripheral ablation, diminishing post-operative spherical aberration).

10 Over time, the response of a cornea to ablative surgery (*e.g.*, LASEK, PRK, LASIK) has been studied. Of a large number of parameters available to measure a cornea, mathematical techniques identified correlations between certain pre-operative

measurements and predicted post-operative results. Thus, customized and customizable corneal ablative systems and methods that benefit from the studies and correlations were

15 developed. The corneal ablative systems and methods depart from conventional ablative techniques that treat the corneal as a piece of plastic and/or that do not consider individual parameters (*e.g.*, modulus of elasticity). Example parameters for which correlations were made include, but are not limited to, modulus of elasticity, corneal acoustic response to ultrasonic excitation, pachymetric profile in multiple meridians, pachymetric asymmetry

20 between vertical and horizontal meridians, magnitude of difference in pachymetry between center and periphery, corneal width, anterior chamber angle and depth, corneal curvature profile in multiple meridians, magnitude of astigmatism, difference in astigmatism between center and periphery topographic response to the cutting of a LASIK

flap. Thus, LASEK, LASIK and/or PRK procedures can be improved by taking pre-operative measurements of the eye, and choosing and/or customizing an ablation algorithm based on correlations in a parametric model. In LASIK, in addition to pre-operative measurements, measurements taken during a surgical procedure facilitate further 5 customizing the ablation algorithm.

Certain illustrative example methods, systems, and computer readable media are described herein in connection with the following description and the annexed drawings. These examples are indicative, however, of but a few of the various ways in which the principles of the methods, systems, computer readable media and so on may be employed 10 and thus are intended to be inclusive of equivalents. Other advantages and novel features may become apparent from the following detailed description when considered in conjunction with the drawings.

Figure 1 illustrates a shape subtraction model.

Figure 2 illustrates an example parametric model system.

15 Figure 3 illustrates an example parametric model method.

Figure 4 illustrates another example parametric model method.

Figure 4a illustrates a regression analysis.

Figure 5 presents a regression analysis of peripheral stromal thickness of the superior region (left plot) and the inferior region (right plot) against curvature.

20 Figure 6 is a flowchart of an example PRK and/or LASEK surgical technique.

Figure 7 is a flowchart of an example LASIK surgical technique.

Figure 8 is a schematic block diagram of an example computing environment with which the example methods and systems described herein can interact.

Figure 9 illustrates an API.

Figure 10 illustrates a data packet.

Figure 11 illustrates subfields in a data packet.

Example methods, systems, and computer media are now described with reference  
5 to the drawings, where like reference numerals are used to refer to like elements  
throughout. In the following description, for purposes of explanation, numerous specific  
details are set forth in order to facilitate thoroughly understanding the methods, systems,  
computer readable media and so on. It may be evident, however, that the methods,  
systems and computer readable media can be practiced without these specific details. In  
10 other instances, well-known structures and devices are shown in block diagram form in  
order to simplify description.

As used in this application, the term “computer component” refers to a computer-related entity, either hardware, firmware, software, a combination thereof, or software in execution. For example, a computer component can be, but is not limited to being, a  
15 process running on a processor, a processor, an object, an executable, a thread of execution, a program and a computer. By way of illustration, both an application running on a server and the server can be computer components. One or more computer components can reside within a process and/or thread of execution and a computer component can be localized on one computer and/or distributed between two or more  
20 computers.

“Signal”, as used herein, includes but is not limited to one or more electrical or optical signals, analog or digital, one or more computer instructions, a bit or bit stream, or the like.

“Software”, as used herein, includes but is not limited to, one or more computer readable and/or executable instructions that cause a computer or other electronic device to perform functions, actions and/or behave in a desired manner. The instructions may be embodied in various forms like routines, algorithms, modules, methods, threads, and/or programs. Software may also be implemented in a variety of executable and/or loadable forms including, but not limited to, a stand-alone program, a function call (local and/or remote), a servelet, an applet, instructions stored in a memory, part of an operating system or browser, and the like. It is to be appreciated that the computer readable and/or executable instructions can be located in one computer component and/or distributed between two or more communicating, co-operating, and/or parallel processing computer components and thus can be loaded and/or executed in serial, parallel, massively parallel and other manners.

Figure 1 is a schematic of the simple “shape-subtraction” paradigm for correcting myopia.  $R_1$  and  $R_2$  are initial and final radii of curvature,  $t$  is the maximum depth of the laser cut, and  $s$  is the diameter of the optical zone. While the shape subtraction model has yielded satisfactory results without considering correlations between pre-operative measurements (and/or measurements taken surgery) and post-operative results, ablative techniques may benefit from such measurements and correlations. For example, Table 1 presents errors encountered in elevation and curvature using conventional techniques.

**TABLE 1: Error between Predicted and Measured Topography after LASIK**

	elevation mean $\pm$ sd (n=10) RMS error	curvature mean $\pm$ sd (n = 10) RMS error
5      central 4mm diameter	$18 \pm 14$ microns	$4.92 \pm 1.89$ diopters
4-9mm diameter zone	$23 \pm 11$ microns	$8.06 \pm 1.76$ diopters
overall	$22 \pm 11$ microns	$6.85 \pm 1.50$ diopters

In LASIK procedures, a flap is cut with a microkeratome to a thickness of approximately 160 microns. Biomechanically, this approximates a 160-micron depth severing of corneal lamellae, similar to an ablation, except no tissue is removed. The amount of corneal flattening produced by the flap cut predicts certain post-operative results. Analyzing topography of the epithelial surface of the cornea, before and after cutting the flap, permits identifying correlations between the topography and certain post-operative results. Thus, this application describes example systems and methods that facilitate updating an ablative algorithm based, at least in part, on correlations associated with corneal measurements taken before and/or after cutting a LASIK flap.

To facilitate identifying correlations between pre-operative measurements and/or measurements taken during surgery and predicted post-operative results, and to facilitate building the parametric model, a study was conducted on 2380 patients who received LASIK. The patients had corneal topography measurements taken pre-operatively and post-operatively.

Correlations were also identified by in vitro studies. In one study, fourteen de-epithelialized eye bank globes from seven donors were subjected in paired control fashion to either broad beam PTK or sham photoablation. Changes in anterior curvature were measured by autokeratometry. Changes in stromal thickness in the vertical meridian were

measured using corneal optical section image analysis. The corneal cross section was divided into five regions for analysis, far superior, near superior, central, near inferior, and far inferior. Analysis included evaluating peripheral thickness changes in geometric bias as predictors of curvature change. Geometric bias was defined as either a myopic or a  
5 hyperopic bias in the pattern of ablation zone thickness loss in order to investigate shape subtraction theories of hyperopic shift in PTK.

Results of this study demonstrated that photoablation caused reductions in keratometric curvature (-6.28 +/- 3.23D, p=0.002) relative to untreated paired controls. The mean keratometric shift measured during sham PTK was not significantly different  
10 from zero (+0.31 +/- 0.85D, p = 0.38). In addition to flattening the spherical curvature component, ablated corneas demonstrated higher absolute magnitudes of keratometric cylinder (2.98 +/- 0.88D) than controls (0.46 +/- 1.72D, p = 0.009), indicating a biomechanical component to the induced cylinder. The relative peripheral stromal thickness change, expressed as the mean pair wise difference (PTK-control), was +57.3  
15 +/- 42.8  $\mu$ m (p = .01) or +8.5 +/- 5.7% (p = 0.1), demonstrating thickening relative to controls. Central curvature shifts were linearly dependent upon regional peripheral stromal thickness changes in ablated and control eyes. Thus, further correlations were identified.

Another in vitro study further examined the relationship between peripheral  
20 stromal thickening and central flattening. A paired control human donor eye study (n = 20) assessed pre-operative topical glutaraldehyde (GTA) treatment as a technique for inhibiting PTK induced peripheral stromal thickening and for attenuating the acute corneal flattening response. Eyes were individually mounted in a custom holder, inflated to

normal intraocular pressure (about 15 mmHg) and de-epithelialized. One cornea of a given donor was immersed in a 15% dextran solution for 40 minutes and transferred to 4% GTA/dextran for an additional 20 minutes. The fellow control was exposed to 15% dextran for 60 minutes. The eyes were subsequently subjected to (1) sham PTK, a same eye control phase incorporated to account for thinning due to intraoperative dehydration,  
5 (2) PTK (5 mm diameter, 100  $\mu\text{m}$  depth) and (3) a one hour hypo-osmotic soak phase designed to assess the anti-swelling activity of stromal cross-linking. A scanning slit topography system (Orbscan) was employed to acquire triplicate thickness and curvature measurements before and after experimental phases. Cross-linking inhibited peripheral stromal thickening during PTK and postoperative hypo-osmotic immersion. In addition,  
10 during PTK, cross-linked corneas demonstrated 36% less hyperopic shift relative to paired controls ( $p = 0.001$ ). The magnitude of this latter effect was linearly dependent upon the magnitude of cross-link mediated suppression of the peripheral thickening response to PTK ( $r = 0.68$ ,  $p = 0.03$ ). Thus, acute hyperopic shifts in a donor model of PTK can be  
15 reduced through pre-operative application of a collagen cross-linking reagent. Thus, example systems and methods described herein rely, at least in part, on correlations associated with this study.

A retrospective analysis of a refractive surgery dataset was performed. The purpose of this analysis was two fold. A first purpose was to demonstrate the ability to perform data analysis on a large set of independent parameters extracted from preoperative clinical data.  
20 A second purpose was to seek preliminary confirmation of the biomechanical response model by analyzing refractive surgery outcomes and their statistical relationship to preoperative measured parameters, which was hypothesized to likely influence this

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response. The dataset used for this preliminary study was based upon a database created from an examination of 18 eyes of 9 patients measured preoperatively with an Orbscan II corneal topography system, at one day, one week, one month and three months after receiving LASIK with a Summit Apex Plus excimer laser. Nearly 200 preoperative

5 parameters were calculated based on data extracted from the Orbscan topographies. These pre-operative parameters consisted of indices related to individual corneal geometries such as shape, pachymetry profiles in multiple meridians, white-to-white measurement of corneal size, anterior chamber depth, as well as surface curvature parameters. All 200 parameters were included as independent variables in a stepwise multiple linear regression  
10 analysis to determine which were significant predictors of the dependent post-operative outcome parameters. Outcome parameters included visual function parameters, such as spherical equivalent refraction, as well as outcome shape parameters based on a Zernike decomposition of the anterior surface elevation topography, measured at 3 months post-operatively.

15 Shown in **Table 2** is the outcome of the stepwise regression with Zernike term #12 ( $Z_{12}$ ) from the anterior surface elevation as the dependent outcome variable.  $Z_{12}$  is the term related to spherical aberration, which has been shown to be significantly increased after refractive surgery. The independent pre-operative parameters in table 2 are ranked based on their partial  $R^2$  value. The strongest pre-operative predictor of post-operative  $Z_{12}$   
20 in the topographic Zernike decomposition was an index labeled pak\_90\_d. This index represents the difference between the central pachymetry and the peripheral pachymetry in a sector around the 90-degree meridian. This single variable accounts for approximately 66% of the variability in post-operative  $Z_{12}$ .

**Table 2:**

Step	Variable Entered	Number Vars In	Partial R-Square	Model R-Square	F Value	Pr > F
1	pak_90_d	1	0.6626	0.6626	27.49	0.0001
2	srax_pak_pr	2	0.1018	0.7644	5.62	0.0339
3	osi_ref_pr	3	0.0972	0.8616	8.42	0.0133
4	ww	4	0.048	0.9095	5.83	0.0343
5	ti_ref_pr	5	0.0307	0.9402	5.14	0.0468
6	ti_tan_pr	6	0.0202	0.9605	4.61	0.0603
7	tano_0_pr	7	0.0302	0.9907	26	0.0009
8	hormwb5_pr	8	0.0062	0.9969	13.95	0.0073
9	dsi_ref_pr	9	0.002	0.9989	10.73	0.0169
10	acd	10	0.0008	0.9997	11.9	0.0183
11	csi_pak_pr	11	0.0003	1	30.8	0.0052
12	refo_pr	12	0	1	16.75	0.0264
13	hormzc5_pr	13	0	1	36.2	0.0265
14	dsi_tan_pr	14	0	1	18578.2	0.0047

The regression plot of parameter pak\_90\_d (difference between the central pachymetry

5 and the peripheral pachymetry around the 90 degree meridian) and Zernike term #12 is shown in **Figure 4a**. The second strongest predictor of  $Z_{12}$  was srax\_pak\_pr, which is another pachymetric profile index. This predictor calculates the angle between the thickest meridian above 180 degrees and the thinnest meridian below 180 degrees. The two-parameter model accounts for 76% of the variability in the outcome variable.

10 Turning now to Fig. 2, an example system 200 for updating a corneal ablation algorithm is illustrated. The system 200 includes a corneal data receiver 210 that receives corneal data 220. The corneal data receiver 210 can be, for example, a computer component. The corneal data 220 may be received, for example, via a computer communication. The corneal data 220 can include, but is not limited to, pre-operative

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measurements, measurements taken during surgery, and/or post-operative measurements.

The corneal data 220 can include, for example, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, corneal acoustic response data, and so on. The corneal data 220 can also include measurements associated with one or more correlations like measurement pachymetry profile being correlated with post-operative result spherical aberration.

The system also includes a parametric model 230 that can be accessed by an ablation algorithm processor 240. The parametric model 230 can be stored, for example, in one or more data stores. By way of illustration, the parametric model 230 may be stored in one or more files, tables, hashes, lists, queues, state machines, data bases, and so on. The data store may reside in one computer component and/or be distributed between two or more communicating, co-operating computer components.

The parametric model 230 facilitates storing relations between one or more measurements, one or more predicted post-operative results, and one or more updates to a corneal ablative procedure. An example relation may take the form:

If  $m1 < v1$  then

$por1 < r1$

thus

$aap1 = aap1 + u1$

endif

where,  $m1$  is a pre-operative measurement,  $v1$  is a value for the pre-operative measurement,  $por1$  is a predicted post-operative result,  $r1$  is a value for the predicted post-operative result,  $aap1$  is an ablation algorithm parameter and  $u1$  is an update amount.  $u1$

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may be a pre-determined, configurable number and/or may be computed according to a formula that depends on one or more measurements like m1.

While the first example relation correlated one input measurement with one predicted post-operative result, it is to be appreciated that more than one input  
5 measurement may be related to a predicted post-operative result. Thus, another example relation may take the form:

If m1 in {a, b} and m2 in {c, d} then

por2 < r2

thus

10 aap2 = aap2 + u2

else if m1 in {a, b} and m2 in {e, f} then

por2 >= r2

thus

aap2 = aap2 - u2

15 end if

where m1 and m2 are pre-operative measurements, {a, b}, {c, d} and {e, f} are ranges of values for the pre-operative measurements, por2 is a predicted post-operative result, r2 is a value for the post-operative result, aap2 is an ablation algorithm parameter and u2 is an update amount. u2 may be a pre-determined, configurable value and/or may  
20 be the result of a function that depends on one or more input measurements like m1 and m2.

While the two example relations are described in a conditional language format, those skilled in the art will appreciate that the relations can be captured and stored in a variety of formats known in the art.

The ablation algorithm processor 240 analyzes the received corneal data 220 in  
5 light of the parametric model 230 and/or one or more correlations stored therein, and identifies ways in which an ablation algorithm can be updated. Thus, one or more ablation algorithms stored, for example, in an ablation algorithm data store 250 can be accessed by the ablation algorithm processor 240 and updated into an updated algorithm 260. The updated algorithm 260 can then be employed in ablation surgery.

10 While the system 200 is illustrated as a connected set of computer components, it is to be appreciated that some computer components may be integrated together into one or more computer components. Similarly, it is to be appreciated that all and/or part of the system 200 may itself be integrated into a surgical tool (e.g. laser system).

In another example, the system 200 may include a data integrator (not illustrated)  
15 that selectively updates the parametric model 230 based on data including, but not limited to, pre-operative data, pre-perturbation data, post-perturbation data, post-ablation data, post-operative data and results, and so on.

Additionally, and/or alternatively, the ablation algorithm processor 240 may initially select an algorithm from the ablation algorithm data store 250 based on the  
20 corneal data 220 and one or more correlations in the parametric model 230. For example, a first set of pre-operative measurement values may indicate that a first ablative algorithm that can be updated in a first set of ways be selected and then updated based on the first set of measurement values and one or more correlations. Similarly, a second set of pre-

operative measurement values may indicate that a second ablative algorithm that can be updated in a second set of ways be selected and then updated based on the second set of measurement values and one or more correlations.

In view of the exemplary systems shown and described herein, example  
5 methodologies that are implemented will be better appreciated with reference to the flow diagrams of Figures 3, 4, 6, and 7. While for purposes of simplicity of explanation, the illustrated methodologies are shown and described as a series of blocks, it is to be appreciated that the methodologies are not limited by the order of the blocks, as some blocks can occur in different orders and/or concurrently with other blocks from that shown  
10 and described. Moreover, less than all the illustrated blocks may be required to implement an example methodology. Furthermore, additional and/or alternative methodologies can employ additional, not illustrated blocks. In one example, methodologies are implemented as computer executable instructions and/or operations, stored on computer readable media including, but not limited to an application specific integrated circuit (ASIC), a compact disc (CD), a digital versatile disk (DVD), a random access memory (RAM), a read only memory (ROM), a programmable read only memory (PROM), an electronically erasable programmable read only memory (EEPROM), a disk, a carrier wave, and a memory stick.  
15

In the flow diagrams, rectangular blocks denote “processing blocks” that may be implemented, for example, in software. Similarly, the diamond shaped blocks denote  
20 “decision blocks” or “flow control blocks” that may also be implemented, for example, in software. Alternatively, and/or additionally, the processing and decision blocks can be implemented in functionally equivalent circuits like a digital signal processor (DSP), an application specific integrated circuit (ASIC), and the like.

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A flow diagram does not depict syntax for any particular programming language, methodology, or style (e.g., procedural, object-oriented). Rather, a flow diagram illustrates functional information one skilled in the art may employ to program software, design circuits, and so on. It is to be appreciated that in some examples, program elements like temporary variables, routine loops, and so on are not shown.

Cutting the flap alters the corneal structure. Corneal measurements taken following cutting the corneal flap are therefore employed by some example methods and systems. As demonstrated above, the microkeratomic incision for the flap produces changes in the cornea. Since cutting the LASIK flap produces a response that facilitates predicting other responses, a method for customizing a refractive ophthalmic algorithm can include pre-operatively measuring the cornea, cutting the flap, measuring the cornea and/or the flap, and adjusting an ablation algorithm based on stored correlations between the measurements and predicted post-operative results.

Turning now to Fig. 3, an example parametric model method 300 for selecting and/or updating an ablative algorithm is presented. At 310, a parametric model is accessed. For example, a data base query can be made, a table can be referenced, a data structure can be accessed, a file can be read, and so on. Data retrieved from the parametric model may, for example, identify candidate correlations and thus identify pre-perturbation data of interest to the method 300.

At 320, the method 300 receives a pre-perturbation data concerning a cornea on which a refractive ophthalmic treatment will be performed. The pre-perturbation data can include, but is not limited to, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, corneal acoustic response and ultrasonic data, wave

front data, and intraocular pressure data, where such data are associated with the cornea before it has been perturbed. The pre-perturbation may be associated with one or more correlations.

Thus, the method facilitates updating an ablative algorithm based on individual measurements before surgery. The measurements have been experimentally and statistically correlated with desired post-operative results. Example measurements include, but are not limited to, modulus of elasticity, corneal acoustic response to ultrasonic excitation, pachymetric profile in multiple meridians, pachymetric asymmetry between vertical and horizontal meridians, magnitude of difference in pachymetry between center and periphery, corneal width, anterior chamber angle and depth, corneal curvature profile in multiple meridians, magnitude of astigmatism, difference in astigmatism between center and periphery topographic response to the cutting of a LASIK flap. Example correlations include, but are not limited to, greater peripheral thickness causing greater spherical aberration. For example, measuring peripheral thickness facilitates predicting post-operative spherical aberration, thus a peripheral thickness measurement in the range {a, b} suggests taking action to increase peripheral ablation, diminishing post-operative spherical aberration. The perturbation can be, for example, a corneal incision, a corneal ablation, a LASIK flap cut, peeling the epithelial layer from the cornea, ultrasounds, and so on. In one embodiment, the perturbation causes the severing of corneal lamellae.

Thus, at 330, the method 300 receives a post-perturbation data. The post-perturbation data can include, but is not limited to, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data,

corneal acoustic response and ultrasonic data, flap thickness data, and intraocular pressure data. The perturbation can be, for example, a corneal incision, a corneal ablation, a LASIK flap cut, an epithelial layer peel, and ultrasounds.

At 340, an ablative surgical algorithm is updated based, at least in part, on the pre-perturbation data, the post-perturbation data, and one or more correlations between one or more of the pre-perturbation data and a predicted post-operative result, the post-perturbation data and a predicted post-operative results, and/or the combination of the three.

The example method 300 thus relies on correlations between pre-perturbation data, post-perturbation data, and predicted post-operative results. For example, a pre-perturbation central flatness measurement, as related to a post-perturbation central flatness measurement may be correlated to a predicted post-operative central flatness result and thus an ablation depth may be updated in the ablation algorithm.

In an extension of method 300 (not illustrated), additional processing is undertaken. This additional processing includes receiving diagnostic data and selectively updating the parametric model based, at least in part, on the post-perturbation data and/or the diagnostic data. In this way, the parametric model can be updated over time to become more complete and thus provide even more accurate predictions. The diagnostic data can include, but is not limited to, corneal acoustic response and ultrasonic data, patient satisfaction data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, flap thickness data; and refractive data.

In one example, the method 300 is run on a stand alone computer component that communicates via computer communications with a surgical laser. In another example, the method is run in a computer component located inside a surgical laser apparatus. In yet another example, portions of the method may run on a stand alone computer

5 component while other portions of the method may run in a computer component located inside a surgical laser apparatus, with the two portions of the method communicating via a computer communication.

Turning now to Fig. 4, an example corneal ablative surgical method 400 is illustrated. The method 400 includes, at 410, measuring a first set of corneal measurements. These measurements are taken before any corneal lamellae are severed.

10 The measurements can include, but are not limited to, corneal acoustic response and ultrasound data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, years of contact lens use data, and prior

15 surgical response data and can be acquired by one or more of corneal topography, optical coherence tomography, wave front analysis, ultrasound, and patient interview.

At 420, based on the data acquired at 410, a corneal ablative algorithm is selectively updated. For example, portions of the algorithm may be enhanced, other portions may be diminished, some may be added, and others may be deleted.

20 Furthermore, an algorithm may initially be chosen based on the data acquired at 410, and then the chosen algorithm may be updated. The choice of an algorithm and its selective updating are based, at least in part, on one or more correlations between the data acquired

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at 410 and one or more desired post-operative results, where the correlations are stored in a parametric model.

At 430, the surgical method includes severing one or more corneal lamellae. The severing can occur as the result of, for example, cutting a LASIK flap, corneal scraping, 5 ablation, epithelial peeling, and the like. In another example, where the surgical method is performed by a surgical apparatus and the method 400 is in operable and/or data communication with the surgical apparatus, the method 400 may not include severing the corneal lamellae. Rather, the method 400 would be confined to performing the algorithm updating based on the measurements and correlations. Thus, rather than being a surgical 10 method, the alternate method would be a surgical support method.

At 440, measuring a second set of corneal measurements occurs. These measurements are taken after one or more corneal lamellae are severed. The measurements can include, but are not limited to, corneal acoustic response and ultrasound data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal 15 curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, years of contact lens use data, and prior surgical response data and can be acquired by one or more of corneal topography, optical coherence tomography, wave front analysis, ultrasound, and patient interview.

At 450, the method includes selectively updating the ablation algorithm based on 20 the second set of corneal measurements and one or more correlations between the measurements and post-operative results stored in a parametric model. Additionally, and/or alternatively, the correlations may relate the first set of corneal measurements and

the second set of corneal measurements with desired post-operative results and suggested algorithm updates.

At 460, the surgical method 400 includes ablating corneal tissue according to the updated algorithm. In one example, the method 400 is run on a stand alone computer component that communicates via computer communications with a surgical laser. In another example, the method 400 is run in a computer component located inside a surgical laser apparatus. In yet another example, portions of the method 400 may run on a stand alone computer component while other portions of the method may run in a computer component located inside a surgical laser apparatus, with the two portions of the method 400 communicating via a computer communication. In another example, where the surgery is performed by a person and/or apparatus in operable and/or data communication with the method 400, then the method 400 may not include 460, this act being performed by an entity related to but not part of the method. Thus, the method 400 would be a surgical support method rather than a surgical method.

In an example method, corneal measurements are taken by methods including, but not limited to, corneal topography, optical coherence tomography, ultrasound (including high frequency ultrasound), refraction, and/or wave front analysis. These measurements are taken before and after the microkeratomic incision for the corneal flap. Ablation algorithm adjustments can thus be made in advance of the ablation in a separate procedure and/or in real time as an intraoperative adjustment after the perturbation (e.g., cut, ablation) but before the ablation.

Example correlations concern factors including, but not limited to, Young's modulus, age, sex, race, years of contact lens wear, thickness, curvature, and corneal size.

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For example, corneas of older individuals tend to be stiffer than those of younger individuals. Thus, myopic procedures generally apply less ablation to older corneas to achieve the same level of correction.

Regression analysis between central curvature change and peripheral elevation  
5 change from thirty subjects who underwent LASIK procedures demonstrated a positive correlation ( $R^2 = 0.56$ ,  $p < 0.0001$ ) indicating that the greater the increase in elevation outside the ablation zone, the greater the flattening curvature change centrally. Thus, this application describes example systems and methods that are adapted based on pre-operative measurements and/or measurements taken during a surgical procedure, based, at  
10 least in part, on this and/or other determined correlations. The correlations can be stored, for example, in a parametric model.

In one case study, regression analysis of central curvature versus peripheral stromal thickness was performed. The plots of this analysis are illustrated in Figure 5. Central curvature has a negative correlation with peripheral thickness, both inferior and  
15 superior, meaning the greater the peripheral thickness, the flatter the central curvature. Figure 5 illustrates a regression analysis of peripheral stromal thickness of the superior region (left) and inferior region (right) against curvature in the central 3 mm region, pre-operatively and at 4 time points post-operatively after PRK in one patient. This demonstrates how central curvature for this patient closely tracked peripheral stromal  
20 thickness over time. Thus, the application describes example systems and methods that are customizable based on pre-operative measurements and/or measurements taken during surgery based, at least in part, on correlations associated with peripheral stromal thickness.

Turning now to Fig. 6, an example corneal ablative algorithm updating method 600 is illustrated. This example method does not employ measurements taken during surgery. Thus, method 600 may be employed, for example, in LASEK and PRK. Additionally, it could be employed in LASIK surgery. The method 600 includes, at 610, accessing a parametric model that stores one or more correlations between pre-operative measurements and post-operative results, which facilitates retrieving and/or generating updates to an ablative algorithm. The correlations are associated with suggested adaptations to ablative algorithms. In one example, the correlations are associated with suggestions for choosing an ablative algorithm that may then be customized based on pre-operative measurements.

At 620, pre-operative data is received. The data can include, but is not limited to, patient visual acuity and visual performance data, corneal acoustic response and ultrasound data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, years of contact lens use data, and a prior surgical response data and can be acquired by one or more of patient questioning, corneal topography, optical coherence tomography, wave front analysis, ultrasound, and patient interview.

At 630, based on the pre-operative data and one or more correlations relating one or more pieces of pre-operative data and predicted post-operative results, a corneal ablative algorithm can be updated. For example, measuring peripheral thickness facilitates predicting post-operative spherical aberration, thus a peripheral thickness measurement

in the range {a, b} suggests taking action to increase peripheral ablation, diminishing post-operative spherical aberration. While a one to one correlation is described, it is to be appreciated that two or more pieces of pre-operative data can be related to one or more predicted post-operative results.

5        In one example, the method 600 is complete at 630. But in another example, the method 600 includes, at 640, ablating tissue in accordance with the updated ablative algorithm. In one example, the method 600 is run on a stand-alone computer component that communicates via computer communications with a surgical laser. In another example, the method 600 is run in a computer component located inside a surgical laser  
10      apparatus. In yet another example, portions of the method 600 may run on a stand alone computer component while other portions of the method 600 may run in a computer component located inside a surgical laser apparatus, with the two portions of the method 600 communicating via a computer communication.

Turning now to Fig. 7, a method 700 for updating an algorithm is illustrated. The  
15      method 700 does not include performing surgery, rather it concerns updating an algorithm that is employed during surgery. Thus, the method 700 may be run remotely from the surgery. For example, a surgeon with a laser surgical tool may be located in a remote location (e.g., hospital overseas). The patient can benefit from processing performed remotely (e.g., hospital in U.S.) by method 700. Thus, the method 700 and the surgeon  
20      and/or laser surgical tool may be in data communication via computer communications. For example, data packets carrying data and/or carrier waves carrying computer executable instructions may pass between the method 700 and the surgeon and/or laser.

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Similarly, other example methods and systems described herein may engage in similar data transfer and/or instruction transfer.

At 710, the method 700 access a model 710 that stores correlations between pre-perturbation data and predicted post-operative results. At 720, pre-perturbation data is received. Based on the data received, its values, and one or more correlations between the data, its values, and a predicted post-operative result(s), at 730, an ablative algorithm is updated. For example, the pre-perturbation data may be related to a post-operative result in a manner that suggests that additional ablation in an additional zone should be undertaken. Thus, an ablation algorithm can be suitably updated. For example, an additional record in a database of locations to be ablated could be added, instructions for ablating to a certain depth could be added to an algorithm, timing instructions could be updated, pre-determined, configurable data values and/or limits could be manipulated, and so on.

At 740, post-perturbation data is received. Then, at 750, based on a correlation(s) between the post-perturbation data and predicted post-operative results, the ablative algorithm can be updated again. Additionally, and/or alternatively, a correlation between pre-perturbation data, post-perturbation data, and a predicted post-operative result can identify algorithm updates.

Those skilled in the art of computer programming, mathematical computer modeling, and/or data base manipulation and administration will readily appreciate that example systems and methods described herein may be embodied in software and/or one or more computer components. Thus, Figure 8 illustrates a computer 800 that includes a processor 802, a memory 804, a disk 806, input/output ports 810, and a network interface

812 operably connected by a bus 808. Executable components of systems described herein may be located on a computer like computer 800. Similarly, computer executable methods described herein may be performed on a computer like computer 800. It is to be appreciated that other computers may also be employed with the systems and methods

5 described herein.

The processor 802 can be a variety of various processors including dual microprocessor and other multi-processor architectures. The memory 804 can include volatile memory and/or non-volatile memory. The non-volatile memory can include, but is not limited to, read only memory (ROM), programmable read only memory (PROM),  
10 electrically programmable read only memory (EPROM), electrically erasable programmable read only memory (EEPROM), and the like. Volatile memory can include, for example, random access memory (RAM), synchronous RAM (SRAM), dynamic RAM (DRAM), synchronous DRAM (SDRAM), double data rate SDRAM (DDR SDRAM), and direct RAM bus RAM (DRRAM). The disk 806 can include, but is not limited to, devices  
15 like a magnetic disk drive, a floppy disk drive, a tape drive, a Zip drive, a flash memory card, and/or a memory stick. Furthermore, the disk 806 can include optical drives like, compact disk ROM (CD-ROM), a CD recordable drive (CD-R drive), a CD rewriteable drive (CD-RW drive) and/or a digital versatile ROM drive (DVD ROM). The memory 804 can store processes 814 and/or data 816, for example. The disk 806 and/or memory  
20 804 can store an operating system that controls and allocates resources of the computer 800.

The bus 808 can be a single internal bus interconnect architecture and/or other bus architectures. The bus 808 can be of a variety of types including, but not limited to, a

memory bus or memory controller, a peripheral bus or external bus, and/or a local bus.

The local bus can be of varieties including, but not limited to, an industrial standard architecture (ISA) bus, a microchannel architecture (MSA) bus, an extended ISA (EISA) bus, a peripheral component interconnect (PCI) bus, a universal serial (USB) bus, and a small computer systems interface (SCSI) bus.

The computer 800 interacts with input/output devices 818 via input/output ports 810. Input/output devices 818 can include, but are not limited to, a keyboard, a microphone, a pointing and selection device, cameras, video cards, displays, and the like. The input/output ports 810 can include but are not limited to, serial ports, parallel ports, and USB ports.

The computer 800 can operate in a network environment and thus is connected to a network 820 by a network interface 812. Through the network 820, the computer 800 may be logically connected to a remote computer 822. The network 820 includes, but is not limited to, local area networks (LAN), wide area networks (WAN), and other networks.

The network interface 812 can connect to local area network technologies including, but not limited to, fiber distributed data interface (FDDI), copper distributed data interface (CDDI), ethernet/IEEE 802.3, token ring/IEEE 802.5, and the like. Similarly, the network interface 812 can connect to wide area network technologies including, but not limited to, point to point links, and circuit switching networks like integrated services digital networks (ISDN), packet switching networks, and digital subscriber lines (DSL).

Pre-operative, postoperative and during surgery measurements can be input to one or more computer components by methods including, but not limited to, key stroke, direct data transfer, and so on. During corneal ablative surgery, the methods described herein

may be performed on a computer system with which a surgical team member communicates. Data may be input to the computer during the surgical process. The method can then update the algorithm that is employed in subsequent steps of the surgery.

The systems, methods, data structures, models and objects described herein may be stored, for example, on a computer readable media. Media can include, but are not limited to, an application specific integrated circuit (ASIC), a compact disc (CD), a digital versatile disk (DVD), a random access memory (RAM), a read only memory (ROM), a programmable read only memory (PROM), a disk, a carrier wave, a memory stick, and the like. Thus, an example computer readable medium can store computer executable instructions for the methods claimed herein and equivalents thereof.

Referring now to Fig. 9, an application programming interface (API) 900 is illustrated providing access to a system 910 for ablative algorithm updating. The API 900 can be employed, for example, by programmers 920 and/or processes 930 to gain access to processing performed by the system 910. For example, a programmer 920 can write a program to access the system 910 (e.g., to invoke its operation, to monitor its operation, to access its functionality) where writing a program is facilitated by the presence of the API 900. Thus, rather than the programmer 920 having to understand the internals of the system 910, the programmer's task is simplified by merely having to learn the interface to the system 910. This facilitates encapsulating the functionality of the system 910 while exposing that functionality. Similarly, the API 900 can be employed to provide data values to the system 910 and/or retrieve data values from the system 910.

For example, a process 930 that retrieves corneal measurements can provide the corneal measurements to the system 910 and/or the programmers 920 via the API 900 by,

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for example, using a call provided in the API 900. Thus, in one example of the API 900, a set of application program interfaces can be stored on a computer-readable medium. The interfaces can be executed by a computer component to gain access to a system for ablative algorithm updating. Interfaces can include, but are not limited to, a first interface

5       940 that facilitates communicating measurement data associated with corneal ablative surgery, a second interface 950 that facilitates communicating correlation data associated with ablative algorithm updating, and a third interface 960 that facilitates communicating algorithm updating data and/or instructions generated from the measurement data and the correlation data by the algorithm updater 910.

10       Referring now to Fig. 10, information can be transmitted between various computer components associated with ablative algorithm updating described herein via a data packet 1000. An exemplary data packet 1000 is shown. The data packet 1000 includes a header field 1010 that includes information such as the length and type of packet. A source identifier 1020 follows the header field 1010 and includes, for example, 15       an address of the computer component from which the packet 1000 originated. Following the source identifier 1020, the packet 1000 includes a destination identifier 1030 that holds, for example, an address of the computer component to which the packet 1000 is ultimately destined. Source and destination identifiers can be, for example, globally unique identifiers (guids), URLs (uniform resource locators), path names, and the like.

20       The data field 1040 in the packet 1000 includes various information intended for the receiving computer component. The data packet 1000 ends with an error detecting and/or correcting 1050 field whereby a computer component can determine if it has properly

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received the packet 1000. While six fields are illustrated in the data packet 1000, it is to be appreciated that a greater and/or lesser number of fields can be present in data packets.

Fig. 11 is a schematic illustration of sub-fields 1100 within the data field 1040 (Fig. 10). The sub-fields 1100 discussed are merely exemplary and it is to be appreciated that a greater and/or lesser number of sub-fields could be employed with various types of data germane to ablative algorithm updating. The sub-fields 1100 include a field 1110 that stores information concerning measurement data (e.g., pre-perturbation, post-perturbation) and a second field 1120 that stores a correlation data relating the measurement data to a predicted post-operative result. The sub-fields 1100 may also include a field 1130 that stores an algorithm update data computed in response to the measurement data 1110 and the correlation data 1120.

What has been described above includes several examples. It is, of course, not possible to describe every conceivable combination of components or methodologies for purposes of describing the methods, systems, computer readable media and so on employed in updating an ablative algorithm. However, one of ordinary skill in the art may recognize that further combinations and permutations are possible. Accordingly, this application is intended to embrace alterations, modifications, and variations that fall within the scope of the appended claims. Furthermore, to the extent that the term "includes" is employed in the detailed description or the claims, it is intended to be inclusive in a manner similar to the term "comprising" as that term is interpreted when employed as a transitional word in a claim.

1. A parametric model based computer implemented method for customizing ablative surgery, comprising:
  - accessing a parametric model;
  - receiving pre-perturbation data concerning a cornea on which a refractive ophthalmic treatment will be performed;
  - receiving post-perturbation data concerning the cornea on which the refractive ophthalmic treatment will be performed; and
  - updating an ablative surgical algorithm based, at least in part, on one or more correlations in the parametric model, where the correlations are between one or more of the pre-perturbation data, the post-perturbation data, and a predicted post-operative result.
2. The method of claim 1, where the perturbation is ultrasound.
3. The method of claim 1, where the perturbation is a corneal incision and severs one or more corneal lamellae.
4. The method of claim 1, where the perturbation is a corneal ablation and severs one or more corneal lamellae.
- 20 5. The method of claim 1, where the perturbation is a LASIK flap cut and severs one or more corneal lamellae.

6. The method of claim 1, where the perturbation is peeling a corneal epithelium and severs one or more corneal lamellae.

7. The method of claim 1, where the pre-perturbation data comprises one or more of  
5 topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, corneal acoustic response and ultrasonic data, wave front data, and intraocular pressure data.

8. The method of claim 1, where the post-perturbation data comprises one or more of  
10 topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, corneal acoustic response and ultrasonic data, wave front data, flap thickness data, and intraocular pressure data.

9. The method of claim 1, comprising:

15 receiving diagnostic data; and  
selectively updating the parametric model based, at least in part, on the diagnostic data, which comprises one or more of corneal acoustic response and ultrasonic data, patient satisfaction data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data,  
20 total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, flap thickness data, and refractive data.

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10. A computer readable medium storing computer executable instructions operable to perform computer executable portions of the method of claim 1.

11. A system for updating an ablation algorithm, comprising:

5           a data receiver for receiving a corneal data;  
              a parametric model for storing correlations between the corneal data, a post-operative result and an ablation algorithm update; and  
              an ablation algorithm processor for updating an ablation algorithm based, at least in part, on the corneal data and the correlations.

10

12. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, and intraocular pressure data measured before a cornea is

15       cut.

13. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, and intraocular pressure data measured before a cornea is  
20       ablated.

14. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, and intraocular pressure data measured before a cornea is scraped.

15. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, and intraocular pressure data measured before a corneal epithelial layer is peeled.

16. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, flap thickness data, and refractive data measured after a cornea is cut.

20 17. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data,

intraocular pressure data, flap thickness data, and refractive data measured after a cornea is ablated.

18. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, flap thickness data, and refractive data measured after a cornea is scraped.

10

19. The system of claim 11, where the corneal data comprises at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, patient halo effect and contour sensitivity data, topographic data, pachymetric data, elevation data, total corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, flap thickness data, and refractive data measured after a corneal epithelial layer is peeled.

20. A computer readable medium storing computer executable components of the system of claim 11.

20

21. A system for customizing an ablation algorithm, comprising:  
means for acquiring a pre-operative data by measuring a cornea pre-operatively;

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means for acquiring a post-perturbation data by measuring a cornea after a perturbation that severs one or more corneal lamellae has been made in the cornea;

means for acquiring a first correlation data between the pre-operative data and a first predicted post-operative result; and

5 means for updating an ablation algorithm based on the first correlation data.

22. The system of claim 21, comprising:

means for acquiring a second correlation data between the post-perturbation data and a second predicted post-operative result; and

10 means for updating the ablation algorithm based on the second correlation data.

23. The system of claim 22, wherein said first and second predictive post-operative

results are each one or more of a predetermined visual performance, a predetermined

corneal shape, a predetermined modulus of elasticity, a predetermined corneal acoustic

15 response to ultrasonic excitation, a predetermined pachymetric profile in multiple

meridians, a predetermined pachymetric asymmetry between vertical and horizontal

meridians, a predetermined magnitude of difference in pachymetry between center and

periphery, a predetermined corneal width, a predetermined anterior chamber angle and

depth, a predetermined corneal curvature profile in multiple meridians, magnitude of

20 astigmatism, a predetermined difference in astigmatism between center and periphery

topographic in response to the perturbation.

24. A system for updating a parametric ablation model, comprising:

a corneal data receiver that receives at least one of a pre-perturbation data, a post-perturbation data, a post-ablation data, and patient visual performance data; and

a data integrator that selectively updates the surgical ablation parametric model

5 based, at least in part, on at least one of, the pre-perturbation data, the post-perturbation data, the post-ablation data and the patient visual performance data.

25. A corneal ablative surgical method, comprising:

measuring a first set of corneal measurements before one or more perturbations;

10 selectively updating a corneal ablative algorithm based on the first set of corneal measurements after the one or more perturbations and one or more first correlations between the first set of corneal measurements and one or more predicted post-operative results, where the correlations are retrievable from a parametric model;

measuring a second set of corneal measurements after one or more perturbations;

15 selectively updating the corneal ablative algorithm based on the second set of corneal measurements and one or more second correlations between the second set of corneal measurements and one or more predicted post-operative results, where the second correlations are retrievable from the parametric model; and

ablating corneal tissue from a cornea in accordance with the updated corneal

20 ablative algorithm.

26. The method of claim 25, where measuring the first set of corneal measurements comprises measuring at least one of corneal acoustic response and ultrasonic data, patient

visual acuity and visual performance data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, contact lens use data, and prior surgical response data by at least one of corneal topography, optical coherence

5 tomography, wave front analysis, ultrasound, and patient interview.

27. The method of claim 25, where measuring the second set of corneal measurements comprises measuring at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, contact lens use data, and prior surgical response data by at least one of corneal topography, optical coherence tomography, wave front analysis, ultrasound, and patient interview.

15 28. A corneal ablative surgical method, comprising:

accessing a parametric model that holds one or more correlations between corneal measurements and post-operative results;

measuring a set of corneal measurements before a corneal ablative procedure;

selectively updating a corneal ablative algorithm based on the set of corneal

20 measurements and the one or more correlations; and

ablating corneal tissue from a cornea in accordance with the updated corneal ablative algorithm.

29. The method of claim 28, where measuring the set of corneal measurements comprises measuring at least one of corneal acoustic response and ultrasonic data, patient visual acuity and visual performance data, topographic data, pachymetric data, elevation data, corneal thickness data, corneal curvature data, wave front data, intraocular pressure data, peripheral stroma thickness data, an age datum, a sex datum, contact lens use data, and prior surgical response data by one or more of corneal topography, optical coherence tomography, wave front analysis, ultrasound, and patient interview.

30. A computer readable medium having stored thereon a data structure employed in updating a corneal ablative algorithm, comprising:

a first field that holds information concerning one or more pre-operative corneal measurements;

a second field that holds information concerning one or more predicted post-operative results, where the predicted post-operative results are derived from the one or more pre-operative corneal measurements via one or more correlations stored in a parametric model; and

a third field that holds information concerning one or more updates to an ablative algorithm where the updates are derived from the pre-operative corneal measurements, the predicted post-operative results and the correlations.

20

31. The computer readable medium of claim 29, comprising:

a fourth field that holds information concerning one or more corneal measurements taken after one or more perturbation; and

where the information stored in the third field is derived from the pre-operative corneal measurements, the corneal measurements taken during a corneal ablative procedure, the predicted post-operative results, and the correlations.

- 5       32. A set of application programming interfaces embodied on a computer readable medium for execution by a computer component in conjunction with updating an ablative algorithm, comprising:
- a first interface for communicating a corneal measurement data;
  - a second interface for communicating a correlation data; and
  - 10           a third interface for communicating an ablative algorithm updating data derived from the corneal measurement data and the correlation data.

- 15       33. In a computer system having a graphical user interface comprising a display and a selection device, a method of providing and selecting from a set of data entries on the display, the method comprising:
- retrieving a set of data entries, each of the data entries representing a choice concerning updating an ablative algorithm based on correlations between corneal measurements and predicted post-operative results;
  - 20           displaying the set of entries on the display;
  - receiving a data entry selection signal indicative of the selection device selecting a selected data entry; and
  - in response to the data entry selection signal, initiating an operation associated with the selected data entry.

34. A computer data signal embodied in a transmission medium, comprising:
  - a first set of instructions for receiving corneal measurements;
  - a second set of instructions for identifying a correlation between a corneal measurement and a predicted post-operative result; and
  - a third set of instructions for updating an ablative algorithm based on the corneal measurements and/or the predicted post-operative result.
- 5
35. A data packet for transmitting an ablative algorithm update, comprising:
  - a first field that stores a corneal measurement data;
  - a second field that stores a correlation data; and
  - a third field that stores an ablative algorithm data derived from the corneal measurement data and the correlation data.
- 10
36. A corneal ablative algorithm updating method, comprising:
  - accessing an ablative algorithm;
  - accessing a parametric model that holds one or more correlations between pre-operative measurements and post-operative results;
  - receiving a pre-operative data; and
  - 20 selectively updating the ablative algorithm based on the pre-operative data and one or more correlations between the pre-operative data and one or more predicted post-operative results.
- 15

37. A corneal ablative algorithm selection and updating method, comprising:

- accessing a parametric model that holds one or more correlations between pre-operative measurements and a predicted post-operative result;
- receiving one or more pre-operative measurements;
- selecting an ablative algorithm based on the pre-operative measurements and one or more correlations; and
- selectively updating the ablative algorithm based on the pre-operative measurements and one or more correlations.

10 38. A laser eye surgery apparatus for performing a customized laser ablation of corneal tissue, comprising:

- a laser for ablating corneal tissue that produces a predicted post-operative result;
- a memory for storing an ablation program that controls the laser;
- a memory for storing a corneal measurement data;
- 15 a memory for storing a parametric model that stores a correlation between the corneal measurement data and the predicted post-operative result; and
- a processor for adapting the ablation program based on the correlation.

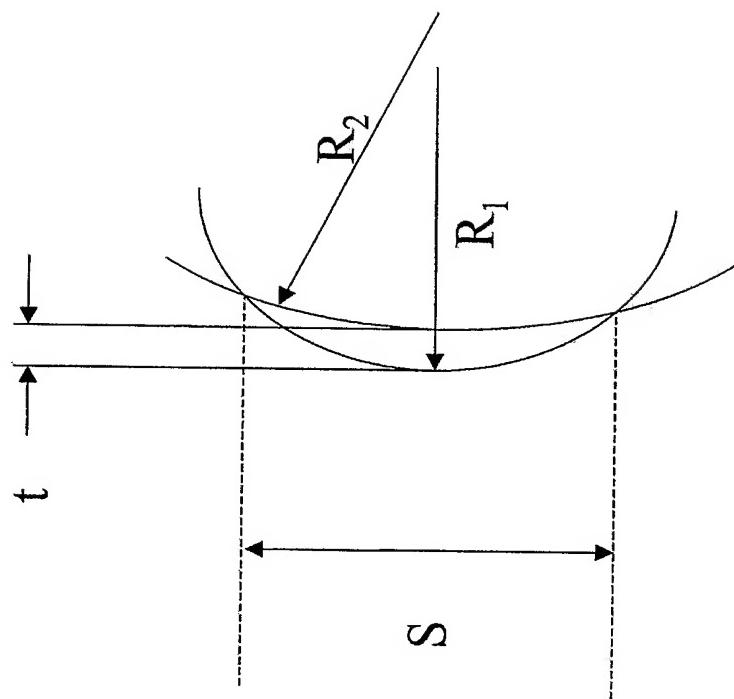
20 39. A laser eye surgery apparatus for performing a customized laser ablation of corneal tissue, comprising:

- a laser for ablating corneal tissue that produces a predicted post-operative result;

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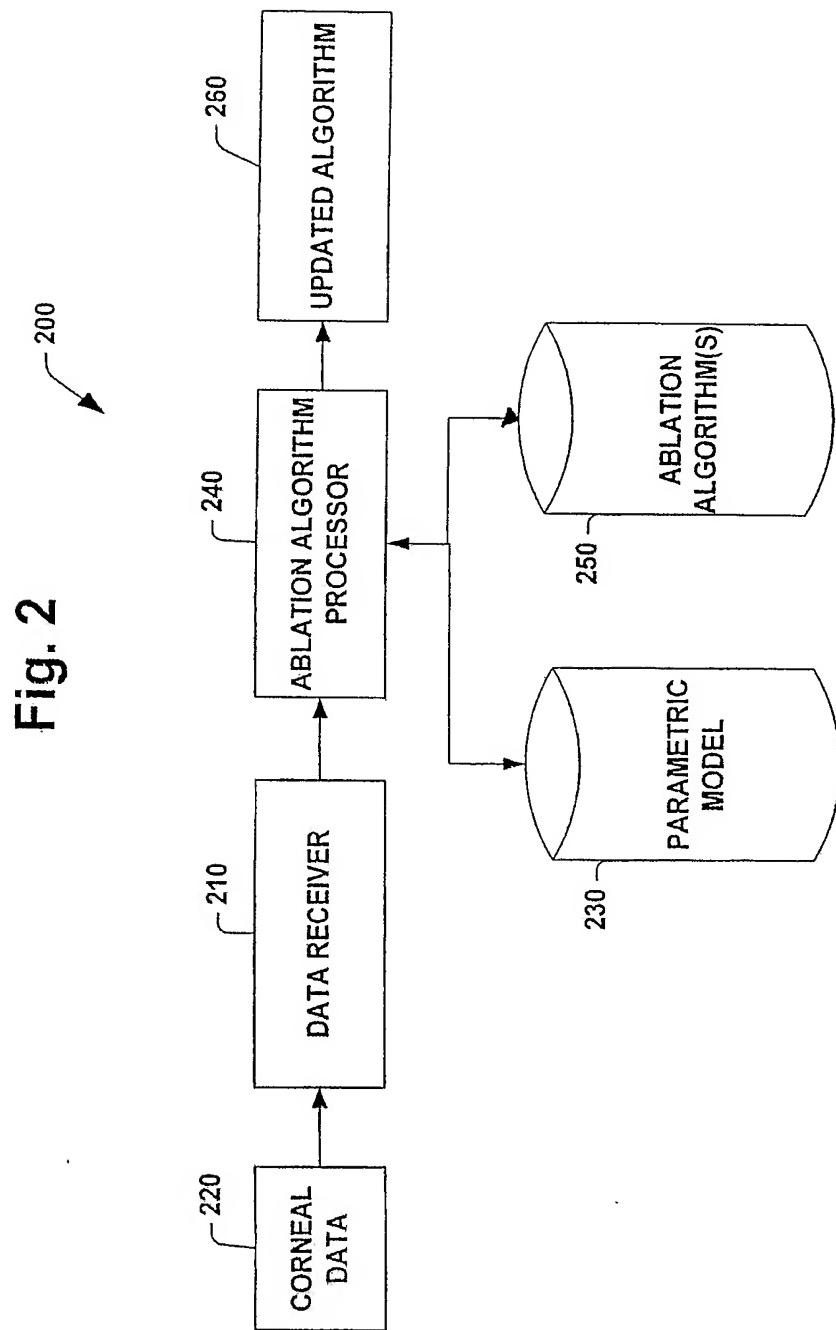
a computer component for receiving an ablation program updated as a result of a correlation between a corneal measurement and the predicted post-operative result; and  
a memory for storing the updated ablation program.

1 / 12

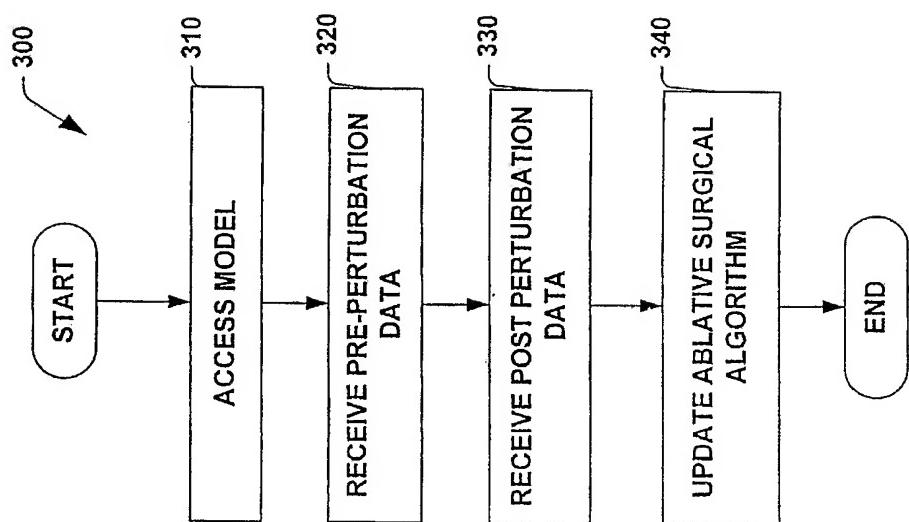


**Fig. 1**

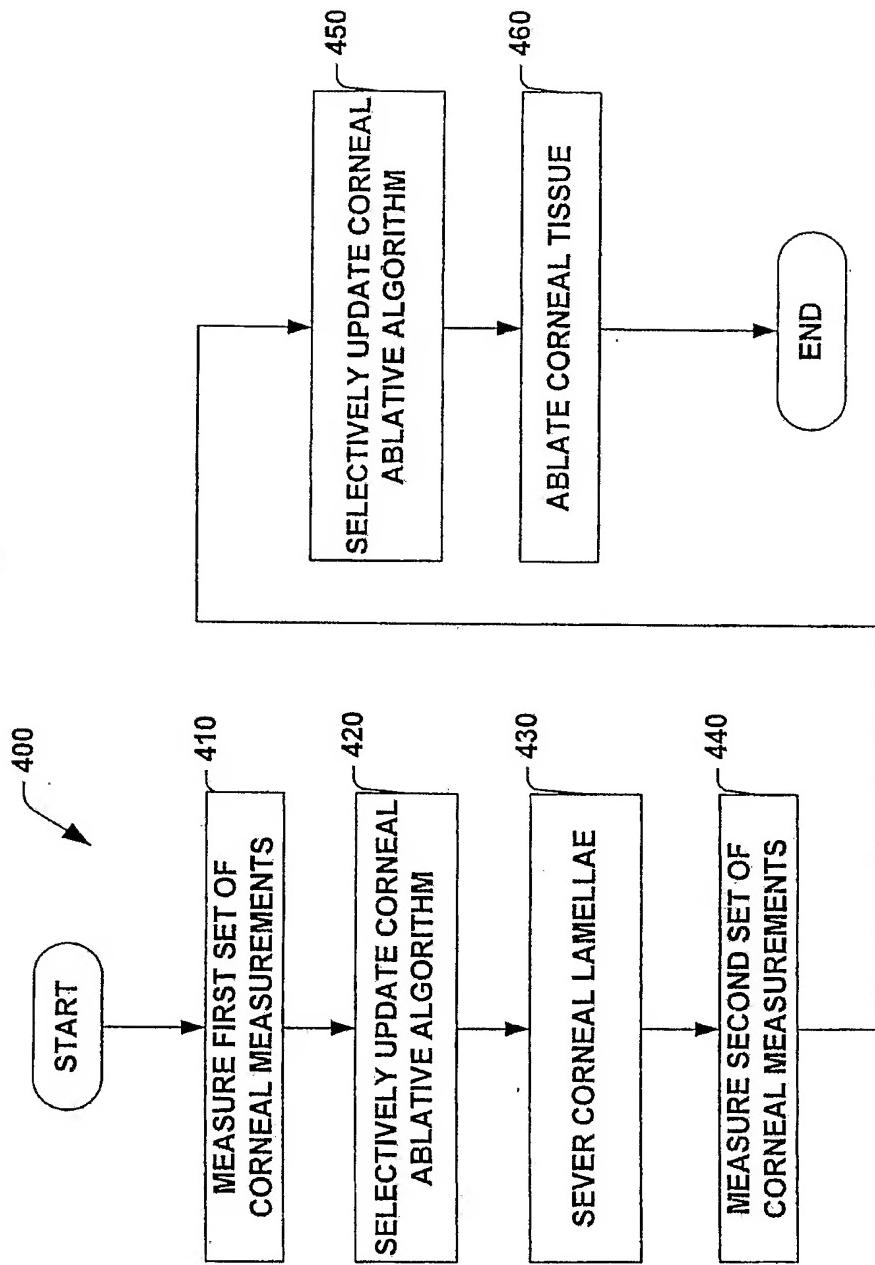
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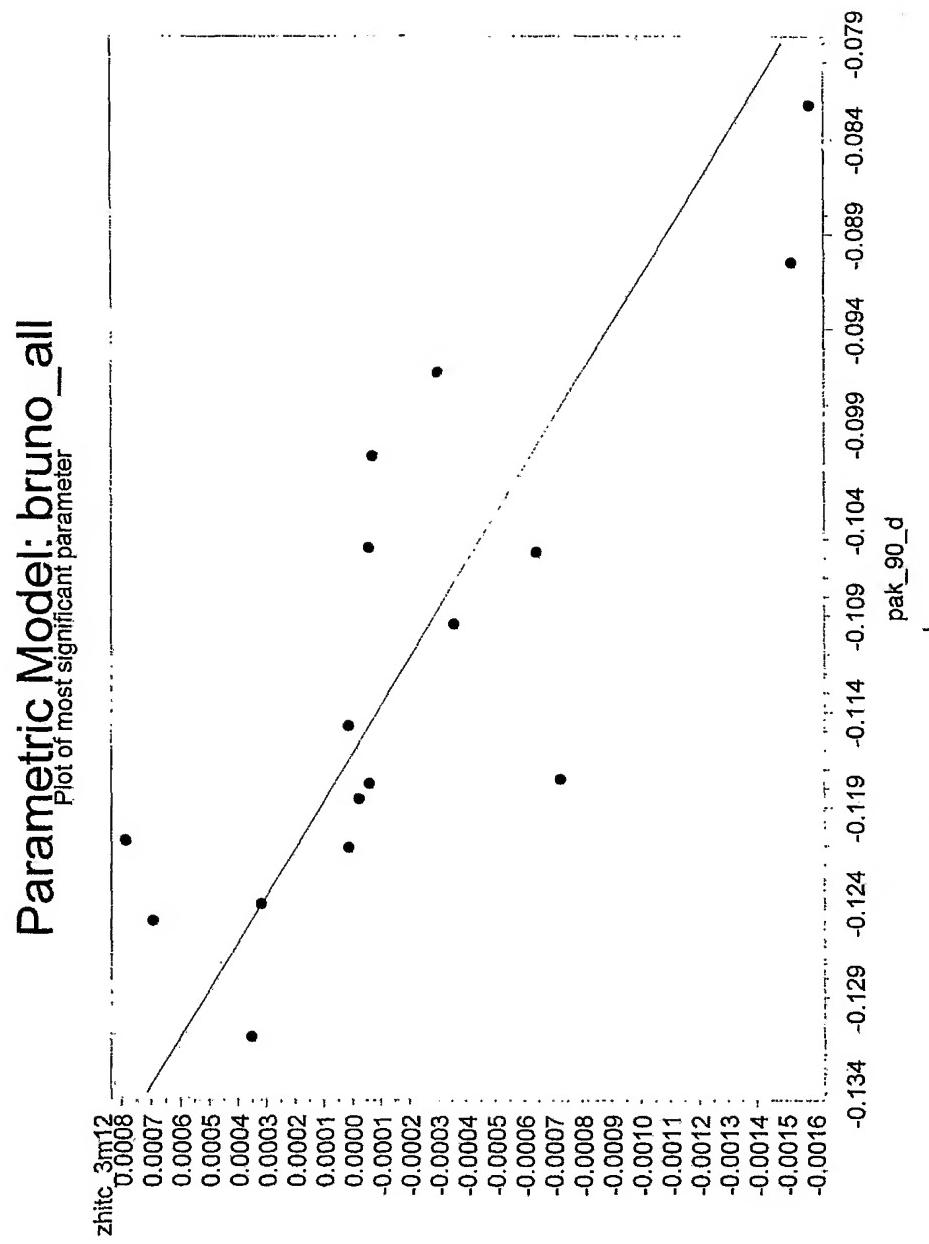
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**Fig. 3**

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**Fig. 4**

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**Fig. 4a**

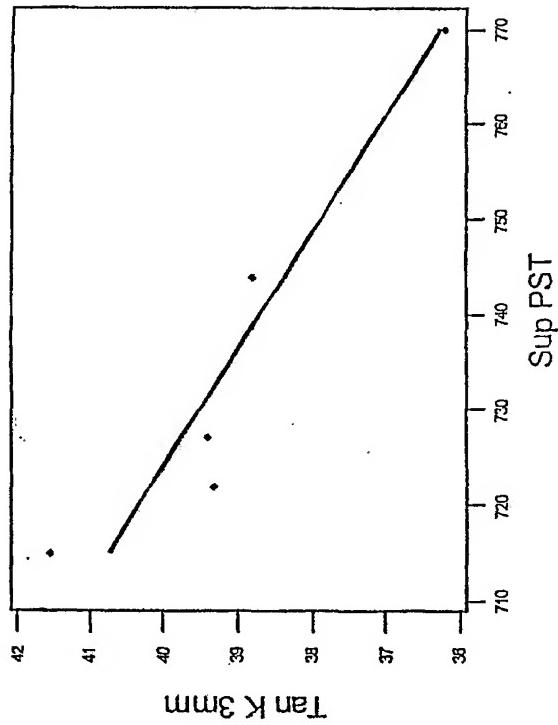
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Fig. 5

Regression Plot

$$Y = 99.1080 + 8.16E-02X$$

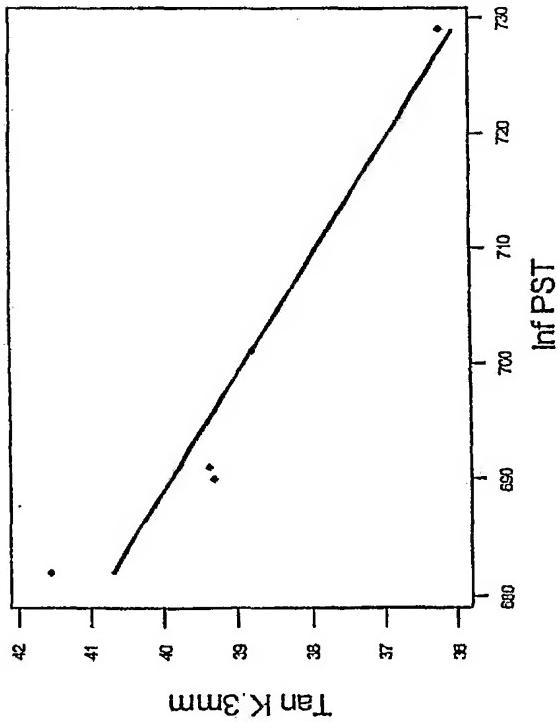
R-Sq = 88.3 %



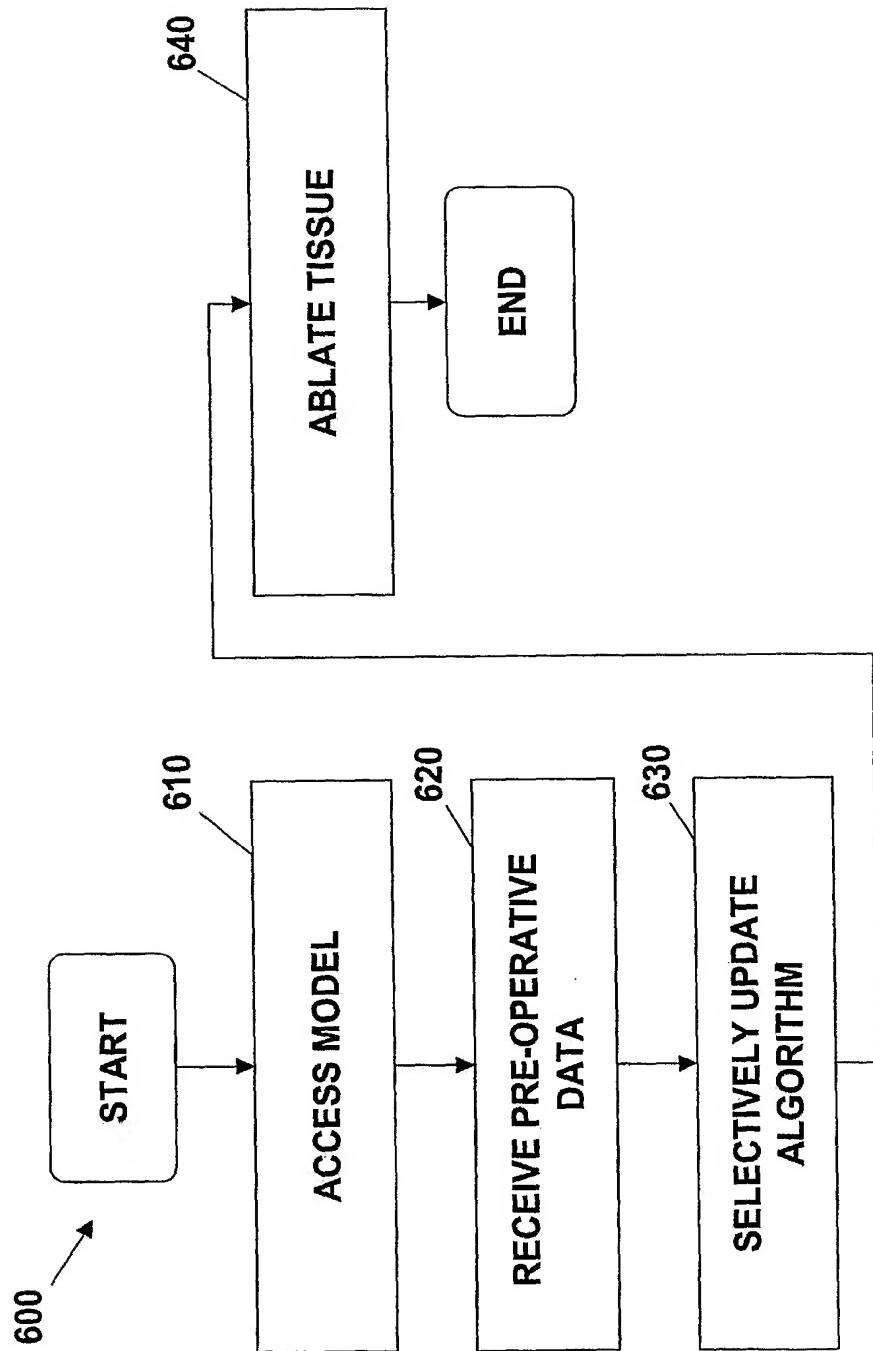
Regression Plot

$$Y = 108.863 - 9.99E-02X$$

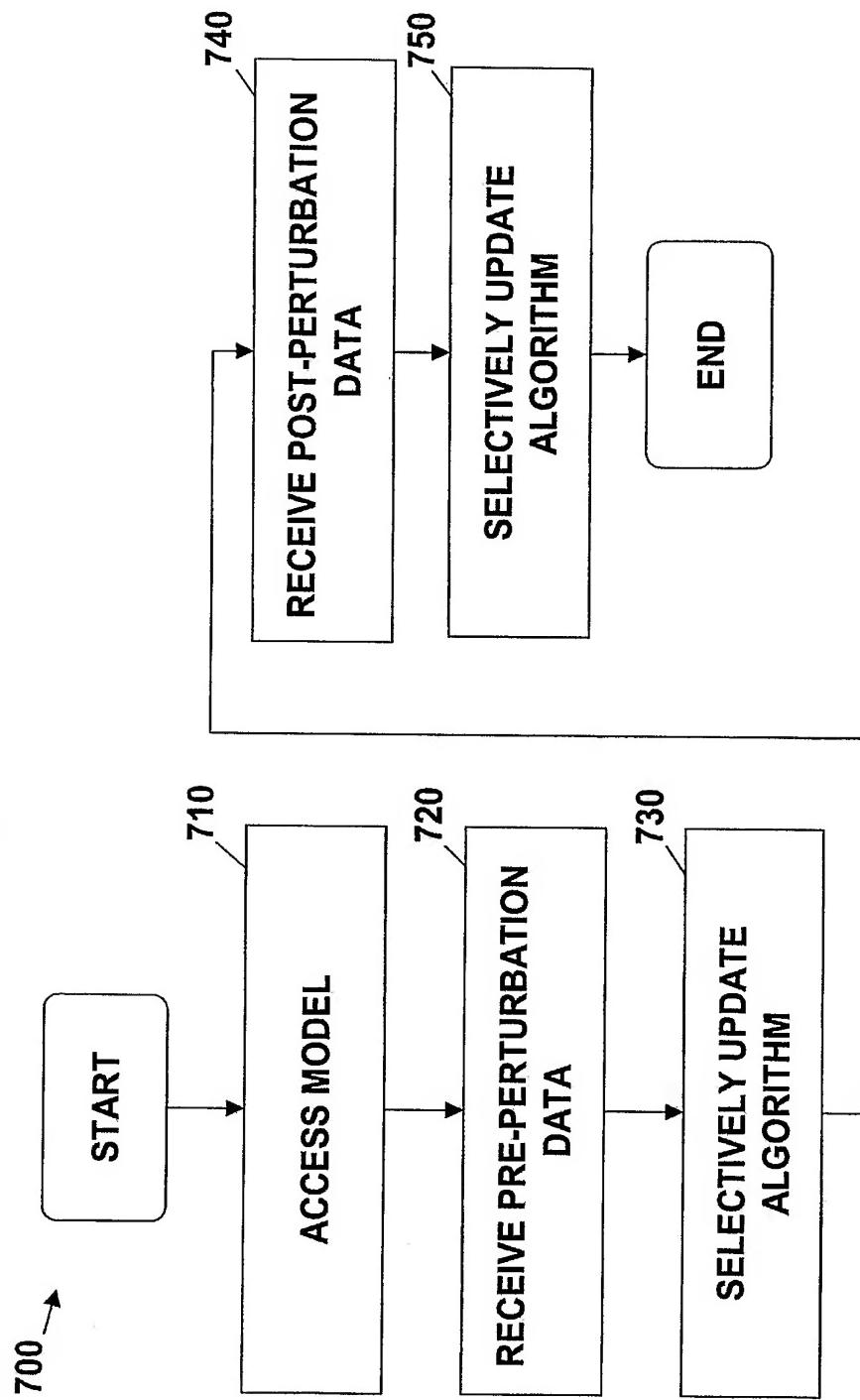
R-Sq = 91.3 %



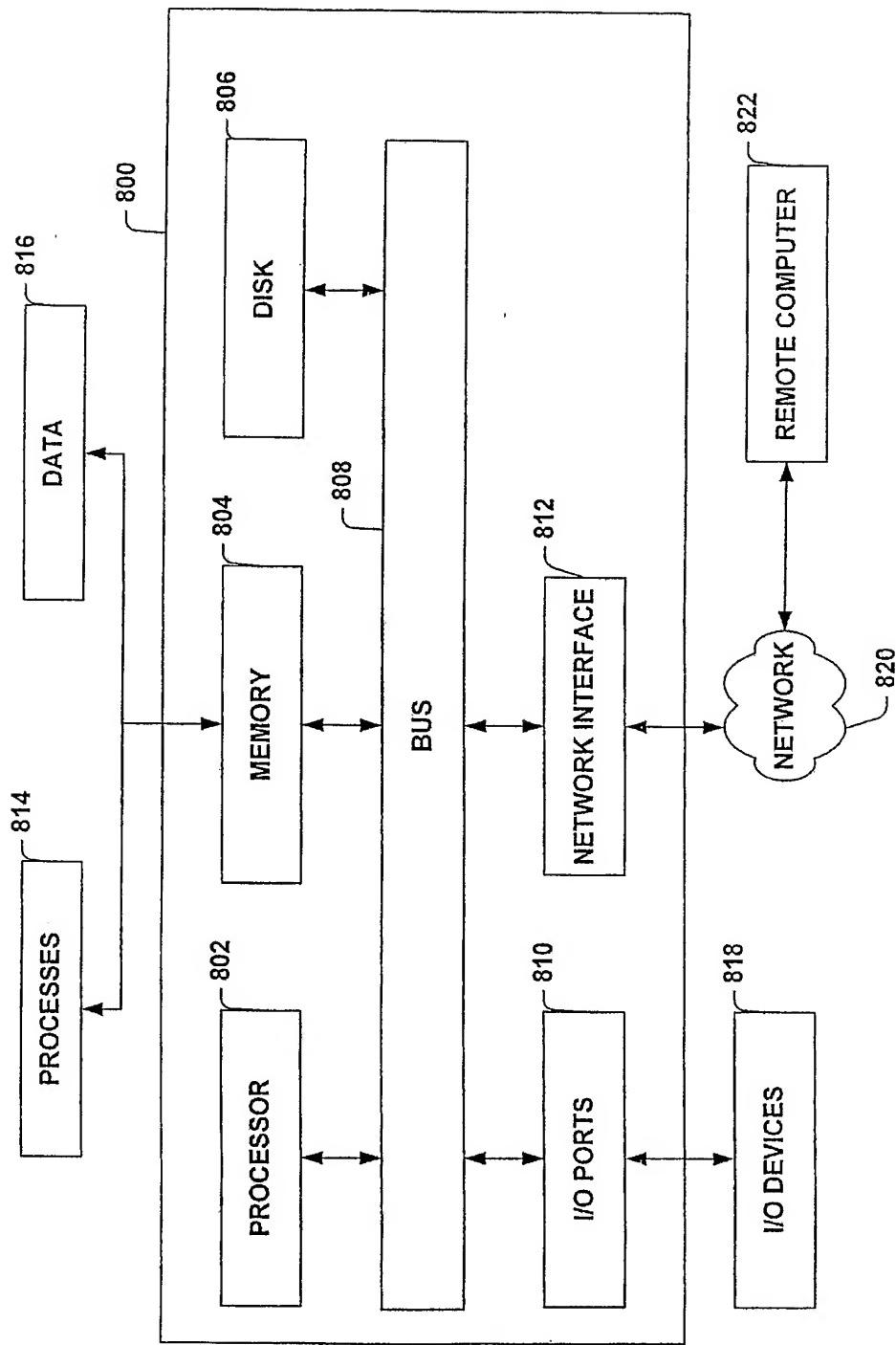
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**Fig. 6**

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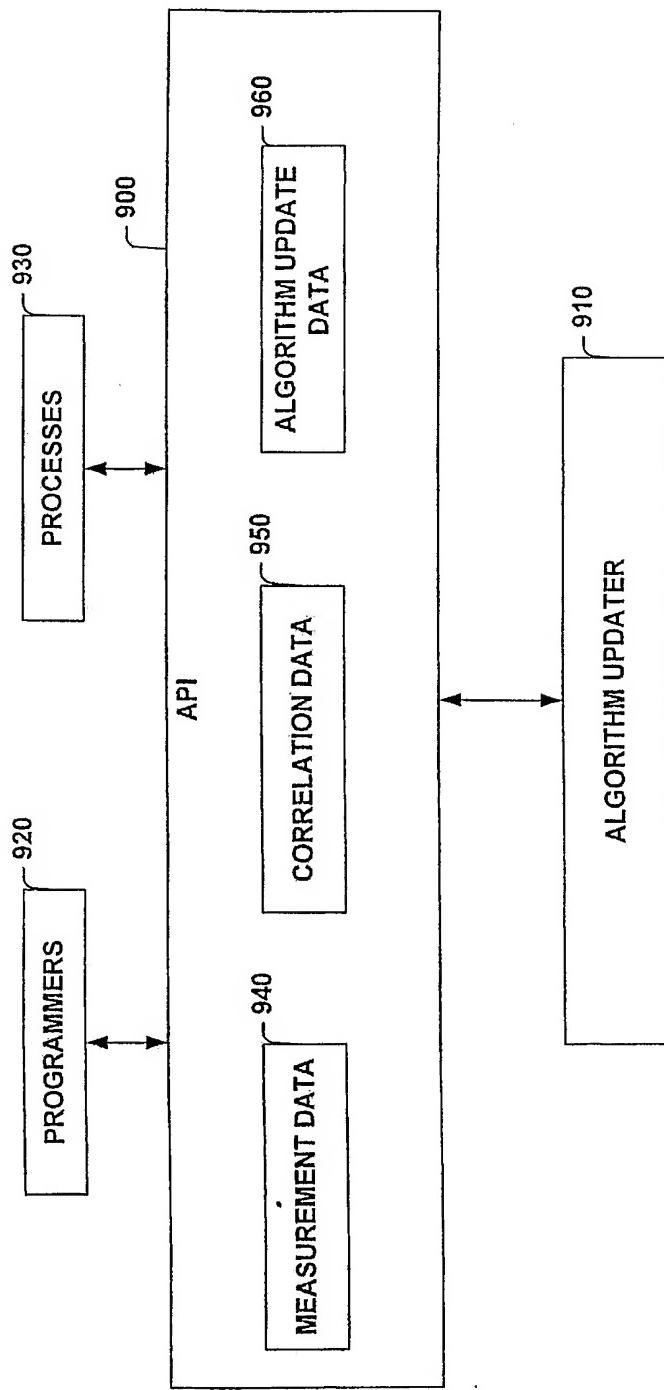
**Fig. 7**

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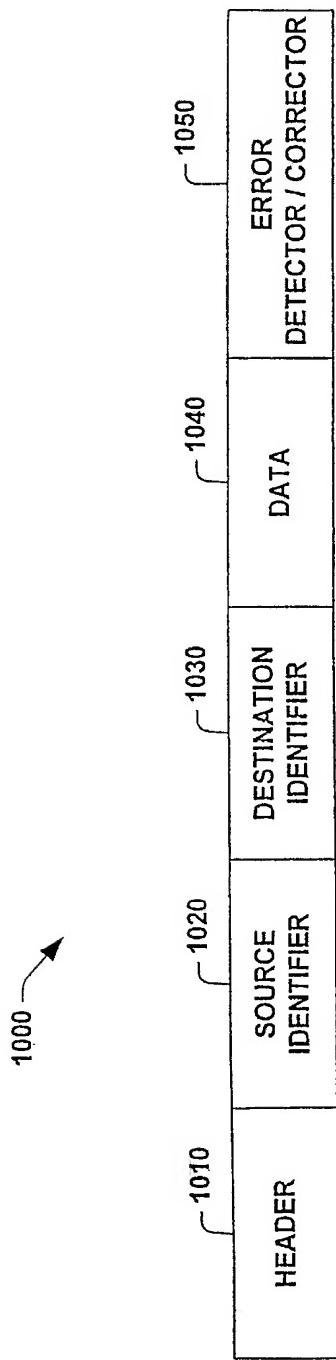
**Fig. 8**

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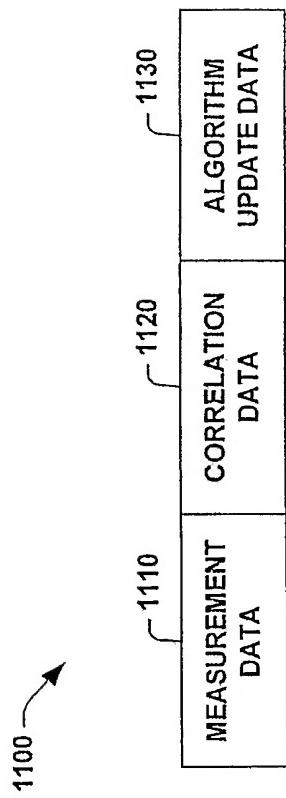
Fig. 9



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**Fig. 10**

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**Fig. 11**

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 03/40302

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 A61F9/01

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 02/07660 A (UNIV OHIO ; KATSUBE NORIKO (US); ROBERTS CYNTHIA (US); DUPPS WILLIAM J) 31 January 2002 (2002-01-31)            page 10, line 10 – line 21            page 29, line 24 – page 30, line 23            claims 4,10</p> <p>-----</p>	1-19

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

3 June 2004

Date of mailing of the international search report

14/06/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL – 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Martelli, L

## **INTERNATIONAL SEARCH REPORT**

International application No.  
**PCT/US 03/40302**

**Box 1 Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: **25–29**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery.**
  2.  Claims Nos.: **20–24, 30–39**  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
**see FURTHER INFORMATION sheet PCT/ISA/210**
  3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this International application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.: \_\_\_\_\_
  4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.: \_\_\_\_\_

## **Remark on Protest**

- The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 25-29

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

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Continuation of Box I.2

Claims Nos.: 20-24,30-39

Independent claims 1, 33, 36, 37 refer to a METHOD of updating an ablative surgical algorithm.

Independent claims 10, 20, 30, 32, 34, 35 refer to a COMPUTER PROGRAM and/or INSTRUCTIONS for updating an ablative surgical algorithm.

Independent claims 11, 21, 24, 28, 39 refer to a SYSTEM comprising means for updating an ablative surgical algorithm.

In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear (and concise), namely:

Claims 1-9 for the method of updating an ablative surgical algorithm.

Claim 10 for the computer program.

Claims 11-19 for the system.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/US 03/40302

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 0207660	A 31-01-2002	AU	7703801 A	05-02-2002
		CA	2416598 A1	31-01-2002
		EP	1301155 A2	16-04-2003
		JP	2004504105 T	12-02-2004
		WO	0207660 A2	31-01-2002